VariLift®-L
Expandable Interbody Fusion Device
A proven solution for stand-alone fusion
VariLift-L Expanable Interbody Fusion Device
Simple, dependable, and proven solution for lumbar fusion

Key benefits:
• Stand-alone
• Mini-incision
• Minimal retraction, no impaction
• Anatomic fit
• Immediate and long-term stability
• Strength and bone-compatibility
• Generous bone graft chamber
• Excellent clinical results

Stand-alone interbody fusion is a reality

The VariLift-L Expandable Interbody Fusion Device is expanded after placement in the disc space—a unique feature that provides secure fixation in stand-alone use. This straight-forward, minimally-invasive approach is supported by a strong body of clinical evidence, making it a simple, dependable, and proven solution for lumbar fusion.

Expanded after insertion, restoring disc height and gripping into the endplates.
Proven.
In over 15 years of clinical use, the VariLift-L has demonstrated excellent clinical outcomes.\textsuperscript{1,2,3,4,5,6}

Stand-alone.
Avoiding the use of pedicle screws may mean a shorter, less invasive procedure—and a quicker recovery.

Straight-forward.
The small pre-expanded size of the device and the intuitive instrumentation provide ease of insertion.

Secure.
When expanded, the device fills the disc space, providing immediate stability and resistance to migration and subsidence over time.

8-year follow-up radiograph of bilateral VariLift-L devices placed via PLIF.
VariLift-L Expanable Interbody Fusion Device
Proven stand-alone performance with over 15 years of clinical use

The VariLift-L device has a long, successful clinical history.
In 2002, Dr. David Attia, the inventor of the VariLift technology, reported his 5-year results, noting:
- a greater than 90% fusion rate
- minimal complications
- 79% of patients had pain reduce from high to low/moderate
- early recovery

Other reports have also verified the viability of the VariLift-L device in the stand-alone PLIF application.

Avoiding disc space infection
The VariLift device is shipped in a single sterile pack, eliminating a potential vector for infection and saving a preparation step. Additionally, in Dr. Warren Neely’s series (at right), the VariLift devices and disc space were flushed with an antibiotic/saline solution before packing with graft.

Two-year Retrospective Clinical Study of the VariLift-L Interbody Fusion Device

Introduction
Dr. Warren Neely has over 10 years of experience using the VariLift-L device, with greater than 1,000 patients operated.

In this study, we present the average 24-month results for a series of 250 of these patients undergoing PLIF with the VariLift-L Expandable Interbody Fusion Device from 2007 to 2009.

Materials/Methods
- Retrospective cohort study
- 250 consecutive patients
- 120 men, 130 women
- Mean age 59.4 year (19 to 83)
- Minimally-invasive midline approach
- Bilateral placement of VariLift devices
Results

Complications:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Rate</th>
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<tbody>
<tr>
<td>Deep Infection*</td>
<td>0.4%</td>
</tr>
<tr>
<td>Adjacent Level Disease</td>
<td>0%</td>
</tr>
<tr>
<td>Return to OR for Supplemental Fixation</td>
<td>0%</td>
</tr>
<tr>
<td>Return to OR for VariLift Reposition</td>
<td>0%</td>
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Radiographic Outcomes:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusion Rate</td>
<td>98%</td>
</tr>
<tr>
<td>Migration**</td>
<td>1.1%</td>
</tr>
<tr>
<td>Subsidence**</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

* n=1, diabetic patient
** Positional change < 2 mm is considered stable7,8
Percentage based on number of levels.

Conclusions

The VariLift-L Expandable Interbody Fusion Devices and procedure used in this series demonstrated excellent clinical outcomes, with:

- Significantly improved pain scores
- A high rate of bony fusion
- Remarkably low rate subsidence
- No re-operation or revisions

Significant Pain Score Improvement

<table>
<thead>
<tr>
<th>Time</th>
<th>High</th>
<th>Medium</th>
<th>Low or None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>248</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>195</td>
<td>28</td>
<td>1</td>
</tr>
<tr>
<td>12 months</td>
<td>138</td>
<td>23</td>
<td>1</td>
</tr>
</tbody>
</table>

*** Follow-up details:

<table>
<thead>
<tr>
<th>Time</th>
<th>Low or None</th>
<th>Medium</th>
<th>High</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>0</td>
<td>2</td>
<td>248</td>
<td>250</td>
</tr>
<tr>
<td>6 months</td>
<td>195</td>
<td>28</td>
<td>1</td>
<td>224</td>
</tr>
<tr>
<td>12 months</td>
<td>138</td>
<td>23</td>
<td>1</td>
<td>162</td>
</tr>
</tbody>
</table>

Pain Level: High | Medium | Low or none
**VariLift-L Expandable Interbody Fusion Device**

**Novel design**\(^9\) expands for an anatomic fit and stability

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**Expands to fill the natural disc space**

In the expanded form, the VariLift device restores disc height, maintains lordosis, gives support to the anterior column, and provides foraminal patency.

**Why titanium-alloy?**

Titanium alloy (Ti6Al4V) is a high-performance material well-known for its strength and biocompatibility for orthopedic applications.\(^{11}\)

The gold standard for achieving secondary fixation in bone-contacting orthopedic applications, roughened titanium-alloy has been shown to promote bony fixation.\(^{12,13,14}\)

The material properties of titanium alloy allow the VariLift device to:

- Incorporate its novel expandability feature
- Meet the biomechanical demands of stand-alone use
- Include large fenestrations and a generous bone graft chamber

**Designed for immediate stability**

As the VariLift device is expanded, ridges on the superior and inferior surface grip into the vertebral endplates, providing stable primary fixation, as demonstrated in laboratory pushout testing.\(^{10}\)

This immediate post-operative stability is crucial to early ambulation and shorter recovery.

**...and to resist migration and subsidence**

The wedge shape and surface characteristics provide resistance to migration over time, with a low rate of subsidence demonstrated clinically.\(^6\)

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*The large lateral fenestrations provide a clear radiological view into the graft chamber.*

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Unexpanded

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Expanded

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*The large lateral fenestrations provide a clear radiological view into the graft chamber.*
Stand-alone capability means a straight-forward, minimally invasive procedure
The VariLift device was designed to achieve primary stability in stand-alone use, without the need for pedicle screws, resulting in a less invasive and shorter procedure.

Preserves posterior anatomy
Destruction of the facet joints has been shown to transfer additional loads to the adjacent discs, possibly accelerating adjacent level disease (ALD).\textsuperscript{15,16} The VariLift procedure preserves the motion at the facets.

Minimal retraction, no impaction
The small semi-circular dura-retractor minimizes retraction against the nerve root and allows mobility within the small incision.

The small pre-expanded size of the VariLift device provides ease of implantation, with no impaction required.

After VariLift device expansion, disc space, lordosis, and foraminal patency are restored.

The surface ridges grip into the bone, providing immediate stability and resistance to migration over time.
VariLift-L Expandable Interbody Fusion Device
Proven for a range of indications

Example cases:
Case 1: Degenerative Disc Disease
Case 2: L5/S1 Disc Herniation
Case 3: Two-Level Fusion
Case 4: Grade 1 Spondylolisthesis
Case 5: Treatment of Adjacent Level Disease

Versatile solution
As demonstrated in these case examples, the VariLift-L device offers maximum flexibility for the surgeon—providing a straight-forward solution for some of even the most challenging fusion cases.

All cases were performed via a minimally-invasive midline PLIF approach, with bilateral placement of VariLift-L devices and no supplemental fixation.

Case 1: Degenerative Disc Disease

44 year-old male patient presented with severe chronic back pain which radiated into the left buttock and leg along the L5 nerve distribution. (a) Pre-operative MRI showing severe disc space narrowing (b) Close-up of radiograph with significant osteophytes projecting into L5-S1 foramina (c) 12-month post-operative radiograph showing mature fusion and stable VariLift devices. At last follow-up, the patient's lower-back pain had resolved. He rapidly returned to normal physical activity, including work as a carpenter and building contractor.
Case 2: L5/S1 Disc Herniation

46 year-old female patient presented with the insidious onset of severe low back, right hip, and leg pain in the L5 and S1 nerve root distributions. She had a unilateral right L5-S1 discectomy performed two years earlier. (a) Pre-operative MRI large right-side disc herniation, with an extruded fragment superior to the disc space (b-c) 12-month post-operative showing stable fusion and no VariLift device subsidence or migration.

Case 3: Two-Level Fusion

23 year-old female patient with a history of back injury presented with low back pain radiating to buttock, posterior thigh, and calf. (a) Pre-operative MRI showing severe herniations at both L4-L5 and L5-S1 with compression of the thecal sac and left nerve roots (b-c) 12-month post-operative radiographs showing mature fusion and stable VariLift devices. The patient had excellent post-operative pain relief of her back, hip, and leg. A the 12-month follow-up she was jogging 2 miles/day.
Case 4: Grade 1 Spondylolisthesis

58 year-old male patient who underwent L2-S1 decompression 15 years previously for removal of a large intradural neurofibroma. Twelve years post-operatively, he was noted to have developed disc space narrowing with an early grade I spondylolisthesis. Two years later, he fell in the shower and developed low back pain which radiated into his hips and legs bilaterally. Plain radiographs and a MRI scan revealed severe disc space narrowing, bilateral foraminal stenosis, and a grade I spondylolisthesis at L4-5. A pre-operative series of (a) neutral, (b) flexion, and (c) extension films showed significant instability.

The patient had immediate post-operative relief of his severe low back and leg pain. Plain radiographs taken 3 months post-operatively indicated excellent position of the VariLift devices at L4-L5 with fusion in progress. A series of (d) neutral, (e) flexion, and (f) extension radiographs showed no instability.
A 63-year-old female patient presented with significant low back, left hip, and leg pain. Her past history included a previous failed L4-5 and L5-S1 posterior fusion, followed one year later by an anterior interbody and posterior pedicle screw fusion at L4-5 and L5-S1, both done in another city. Her recurrent symptoms began several years following her anterior/posterior fusion. (a) MRI scans and (b) plain radiographs revealed a solid L4-S1 fusion, with significant degenerative disc disease and disc protrusion at L3-4 with chronic instability.

Clinical follow-up was conducted at 6 weeks, 6 months, and 2 years, with no complications noted. Two-year follow-up radiographs showed a stable fusion and no significant device subsidence or migration. (c) A/P neutral (d) Lateral flexion.
The VariLift Expandable Interbody Fusion System is a simplified approach to spinal fixation—with low impact insertion and anatomic design that preserves the native anatomy. The strong body of clinical evidence—including over a decade of experience in thousands of patients—shows that stand-alone interbody fusion is a proven reality.

References